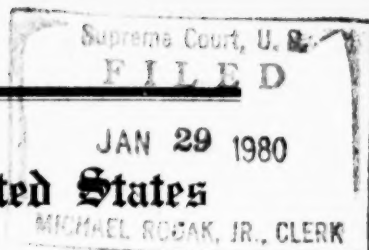

IN THE
Supreme Court of the United States
OCTOBER TERM, 1979



No. 79-136

SIDNEY A. DIAMOND, COMMISSIONER OF PATENTS AND
TRADEMARKS, *Petitioner*

v.

ANANDA M. CHAKRABARTY, *Respondent*

**On Writ of Certiorari to the United States
Court of Customs and Patent Appeals**

**BRIEF ON BEHALF OF THE PHARMACEUTICAL
MANUFACTURERS ASSOCIATION,
AMICUS CURIAE**

DONALD R. DUNNER
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER
1775 K Street, N.W.
Washington, D.C. 20006

Of Counsel:

CHARLES E. LIPSEY
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER
1775 K Street, N.W.
Washington, D.C. 20006

BRUCE J. BRENNAN
EDWIN C. MULCAHY
Pharmaceutical Manufacturers
Association
1155 15th St., N.W.
Washington, D.C. 20005

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**BRIEF ON BEHALF OF THE PHARMACEUTICAL
MANUFACTURERS ASSOCIATION,
AMICUS CURIAE**

I. INTRODUCTION AND INTEREST OF AMICUS CURIAE

THREAT TO FISHING, TOURISM
OIL SPILL PERILS FRENCH COAST

Thousands of barrels of oil from the wrecked American-owned supertanker Amoco Cadiz swept down the picturesque Brittany coast yesterday, blackening beaches and menacing ports along 40 miles of shorelines.

.

Officials fear the spill could become France's worst ecological disaster before it is brought under control.

The Washington Post, Sunday, March 19, 1978, at A-1.

Given the magnitude of this disaster, one would have thought that the discovery of a means for mitigating or eliminating totally the effects of such an oil spill would be entitled to patent protection, assuming the requisite novelty and nonobviousness. In *Application of Chakrabarty*, 596 F.2d 952 (C.C.P.A. 1979), a four-judge majority of the U.S. Court of Customs and Patent Appeals (CCPA) again¹ held exactly that: that the inventor of a new strain of microorganism (bacteria) alleged to be capable of simultaneously degrading several different components of crude oil, with the result that degradation occurs more rapidly, was entitled to patent protection. On October 29, 1979, this Court granted the Government's petition for a writ of certiorari in the *Chakrabarty* case.

Petitioner, supported by *Amicus* People's Business Commission (PBC), urges this Court to reverse the CCPA determination of patentability. It is their position that a patent on the Chakrabarty microorganism should be denied solely because that organism is "living." This contention is made notwithstanding the

¹ The court had earlier reached the same conclusion in *Application of Chakrabarty*, 571 F.2d 40 (C.C.P.A. 1978), *vacated and petition for cert. dismissed*, 99 S. Ct. 44 (1978). The CCPA recalled its original mandate in the *Chakrabarty* case to allow that decision to be reconsidered along with *Application of Bergy*, 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub. nom. Parker v. Bergy*, 438 U.S. 902 (1978). This Court vacated the original decision in *Bergy* and remanded for consideration in light of *Parker v. Flook*, 437 U.S. 584 (1978).

grudging concession of PBC that the granting of patents on subject matter such as was invented by Chakrabarty would generate a greater momentum in research and development leading to the rapid application of this technology in many aspects of the nation's economic life (PBC Brief at 3).

Both Petitioner and PBC urge the same result for the biologically pure microorganism culture forming the subject matter of the Bergy invention. That case has been mooted by virtue of the abandonment of the underlying patent application, and the appeal with respect to it has been dismissed.²

Amicus Pharmaceutical Manufacturers Association (PMA) has a deep interest in the aforesaid position taken by Petitioner and PBC. More specifically, the Chakrabarty microorganism resulted from the newly emerging group of technologies sometimes referred to as "genetic engineering." These technologies include, *inter alia*, mutation and isolation of organisms and recombinant DNA techniques.³ It has been predicted that "the first major commercial impact of present-day DNA research will be seen in the pharmaceutical industry."⁴

While the Chakrabarty microorganism is economically important for what it consumes, other modified organisms are and will become important for the ma-

² In light of the dismissal of the *Bergy* appeal, discussion in this brief will refer to that subject matter only to the extent it is helpful in understanding the issues in the present appeal.

³ *Where Genetic Engineering Will Change Industry*, Business Week, October 22, 1979, at 160.

⁴ Tullis, *Recombinant DNA Research*, Morgan, Stanley & Co. Investment Research Note, September 11, 1979, at 1.

terials they produce. Where insulin for diabetic treatment has formerly been extracted from animal pancreases, hitherto unavailable *human* insulin is now being produced by a modified microorganism.⁵ Where treatment of one child for dwarfism previously required extraction of human growth hormone from 50 cadavers per year, that same hormone can now be synthesized through the use of a modified microorganism.⁶ In the offing is the synthetic production by microorganisms of interferon, a presently expensive natural body substance which stimulates immune reactions and which may be effective in treatment of numerous viral diseases and possibly in cancer therapy. Also in the offing is microbiological production of human blood fractions, including those fractions used to treat hemophilia which must now be produced from pooled human plasma sources.⁷

Potential applications of this new technology in nonpharmaceutical areas include industrial waste dis-

⁵ Begley et al., *The DNA Industry*, Newsweek, August 20, 1979, at 53. Bacterial insulin production is expected to be 30 to 50% cheaper than conventional technology. Wade, *Recombinant DNA: Warming Up for the Big Payoff*, 206 Science 464 (1979).

⁶ Begley, *supra* note 5, at 53. Indeed, researchers using recombinant DNA techniques produced as much of a brain hormone overnight in a 2-gallon jug of altered bacterial culture as Nobel laureates Guillemin and Schalley (1977) were able to extract in a year-long process from the brains of 500,000 sheep. *Hearings on Regulation of Recombinant DNA Research before the House Subcommittee on Science, Technology and Space*, 95th Cong. 1st Sess. 56 (1977) (Statement of Paul Berg).

⁷ Tullis, *supra* note 4, at 5. Indeed, synthetic interferon is no longer simply in the offing. As this brief was being prepared, newspapers across the country reported that research on interferon had come to fruition. See, e.g., Russell, *Disease Fighter Interferon Synthesized*, The Washington Star, January 17, 1980, at A-1.

posal, cost-efficient production of alcohol from inexpensive biomass for use in gasohol production and the production of synthetic organic chemicals of all types for the chemical industry.⁸ It has been said that the promise is nothing less than "the possibility of building a sustainable future based on renewable resources."⁹ In terms of economics, we are talking about "billion-dollar possibilities."¹⁰ Pharmaceutical companies will occupy a unique position even in these non-pharmaceutical areas, since "except for the drug companies, which use large-scale fermentation processes to manufacture drugs, most companies have little or no experience with culturing living organisms."¹¹

The Pharmaceutical Manufacturers Association is a voluntary, non-profit association composed of 143 members engaged in the discovery, development, manufacture and marketing of prescription and ethically promoted drugs, medical devices and diagnostic products. Some of PMA's members are engaged in genetic engineering research, and it is probable that others will soon be entering this promising field. Since the United States pharmaceutical industry has been greatly encouraged by the patent protection hitherto afforded the fruits of its research, *Amicus* PMA files this brief on behalf of its members in order to assure the continued availability of meaningful patent pro-

⁸ Tullis, *supra* note 4, at 3; Business Week, *supra* note 3, at 160, 168.

⁹ Business Week, *supra* note 3, at page 160, quoting Zsolt Harsanyi of the Office of Technology Assessment.

¹⁰ Begley et al., *supra* note 5, at 53.

¹¹ Business Week, *supra* note 3, at 172. See also Tullis, *supra* note 4, at 6.

tection as we stand on the threshold of development of this potentially revolutionary technology.

All parties have consented to the filing of this *Amicus* brief by letter, the originals of which are being filed concurrently with the Clerk.

II. SUMMARY OF ARGUMENT

This case does not involve a number of issues raised both by *Amicus* PBC and Petitioner.

It does not involve the patenting of phenomena of nature or the like. Petitioner expressly conceded that the Chakrabarty microorganism is not a product of nature, and prior decisions of this Court have clearly indicated that such a microorganism is not unpatentable as a product or phenomenon of nature.

Whether or not the technology of genetic engineering is in the public interest should have no impact on the outcome of this case, since (1) there is no doubt that the granting of patents on living organisms will promote the progress of the useful arts, (2) the absence of patents on living organisms will not preclude research or commercial exploitation in areas such as genetic engineering absent legislation by Congress, and will only serve to limit public disclosure of the technology, and (3) the "sky-is-falling" arguments made against the patenting of living organisms could have been made against a multitude of inanimate technologies which have contributed heavily to this country's progress.

The potential patenting of higher life forms is not before the Court in this case, and need not be decided in order to resolve the issues presented by the Chakrabarty invention. Aside from the fact that courts do

not shrink from difficult decisions, the all-or-nothing argument of Petitioner and *Amicus* PBC is unsound.

The practical success or failure of the patent acts covering plants is irrelevant to the issues in this case and, in any event, the argument grounded on its alleged failure is based on faulty factual assumptions.

The holding below is totally compatible with an almost 200-year old statutory scheme and the historical application of the patent laws. Aside from the fact that the holding does not represent an extension of the patent laws, the statutory scheme since 1790 has contemplated patenting of new and unforeseen technologies, has been applied to new technologies as they developed, including those related to living organisms, and its application to new and unforeseen technologies best achieves the constitutional purpose of promoting the useful arts.

Contrary to Petitioner's view, it was not the general understanding prior to the decision below that legislation was needed if the patent laws were to be applied to microorganisms.

Congress did not intend to exclude microorganisms from the scope of 35 U.S.C. § 101. Petitioner's position that the Plant Patent Act of 1930 and the Plant Variety Protection Act preclude construction of Section 101 to cover microorganisms is based on fallacious assumptions and unduly expansive interpretations of the legislative history of these acts. Not only did these acts have nothing to do with microorganisms, but the views of a subsequent Congress are of little value in determining the intent of a prior Congress. Moreover, the collateral elements of this legislative history do not establish a Congressional intention to exclude microorganisms from the scope of the patent laws.

III. ARGUMENT

A. What This Case Does Not Involve

1. The issues raised in *Chakrabarty* do not involve the patenting of phenomena of nature or the like

There have been many cases decided by this Court in which the issue presented involved the unpatentability of phenomena of nature and scientific principles in one form or another. Notable among these are *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1930), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *Parker v. Flook*, 437 U.S. 584 (1978). *Chakrabarty* is not such a case. Neither Petitioner nor PBC seriously contends that this case involves a product of nature.¹² Indeed, Petitioner expressly concedes that the *Chakrabarty* microorganism is *not* a product of nature (Pet. Brief at 33, n.39). An assertion that the invention involved was a product

¹² *Amicus* PBC half-heartedly contends at page 13, note 12 of its brief, that all forms of life are the "epitomy of laws of nature," which are allegedly unpatentable under *Flook*. Manifestly, living organisms no more epitomize the laws of nature than do other forms of matter in that all things, animate or inanimate, operate and interact only in accordance with the laws of nature. Even PBC does not contend that the claimed *Chakrabarty* invention is a law of nature, nor can it assert that it is a "product of nature" for reasons noted hereinafter.

Similarly, Petitioner's contention at page 23, n. 26 of its brief that, on the authority of *Flook*, living organisms are not the kind of discovery that the patent statute was designed to protect, is not based on an assertion that the claimed invention here in issue is a natural law or phenomenon. Indeed, the government's assertion is stated to be wholly independent of the scope of the patent claims presented. Rather, the contention is plainly seen to be part and parcel of Petitioner's assertion that implicit in various acts of Congress is the intention not to include living things within the general patent laws. This issue is addressed in detail in Section D, *infra*.

of nature was abandoned by the Patent and Trademark Office (PTO) Board of Appeals in *Chakrabarty*,¹³ was expressly rejected by the CCPA majority¹⁴ and need not be resurrected before this Court.

Moreover, the prior decisions of this Court clearly indicate that the *Chakrabarty* invention is *not* unpatentable as a product or phenomenon of nature. In *American Fruit*, a borax-impregnated orange was held unpatentable as a product of nature because borax impregnation did not produce an article having "a new or distinctive form, quality, or property." 283 U.S. at 11-12. In *Funk*, this Court held a mixture of non-inhibitive strains of bacteria unpatentable because the combination produced neither "new bacteria" nor an "enlargement of the range of their utility." 333 U.S. at 131. One must strain to deny that the normal meaning of the quoted passages from *American Fruit* and *Funk* would militate in favor of the patentability of the totally new, modified microorganism of *Chakrabarty*.¹⁵

¹³ This fact was noted in the CCPA's original *Chakrabarty* opinion, 571 F.2d at 42.

¹⁴ 596 F.2d at 973.

¹⁵ By way of further example, the CCPA majority noted that the naturally-occurring *Bergy* organism was quite useless before it was converted into the claimed biologically pure culture, 596 F.2d at 972, in contrast to the situation in *American Fruit* where both the starting material and the end product was an orange—just as edible and tasty before as after borax impregnation. The advance from uselessness to usefulness would appear to be the type of new or distinctive quality or property envisioned by *American Fruit* or the "enlargement of utility" contemplated by *Funk* as the indicium of an article of manufacture. Indeed, this is precisely the rationale of lower federal court decisions rendered after *Funk* and *American Fruit*. See, e.g., *Merek & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156 (4th Cir. 1958),

2. Whether or not the technology of genetic engineering is in the public interest should have no impact on the outcome of this case

a. *There is no doubt that granting patents on living organisms will promote the progress of the useful arts*

The constitutional mandate of the patent system is to promote the progress of the useful arts. There is virtual unanimity of opinion that genetic engineering technologies will greatly advance the state of numerous and varied technological arts including the pharmaceutical, energy and agricultural industries. There is also virtual unanimity of opinion that the availability of patent protection will, as it has in the pharmaceutical industry, promote research and development in genetic engineering technologies. Indeed, the brief of *Amicus* PBC, one of genetic engineering's most vocal critics, is replete with concessions that the issuance of patents in this area will perform the function intended by the framers of the Constitution and the

holding purified vitamin B₁₂ to be a new and useful composition rather than a product of nature.

The *Merck* approach has well served to promote the progress of the useful arts, particularly in the pharmaceutical technologies, and was earlier invoked to uphold the patentability of such useful materials as purified adrenalin and purified aspirin. *See* *Parke-Davis & Co. v. H. K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912), affirming in pertinent part the district court's decision authored by Judge Learned Hand, 189 F. 95 (S.D.N.Y. 1911), and *Keuhmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir.), *cert. denied*, 220 U.S. 622 (1910).

drafters of the patent statutes.¹⁶ PBC is not alone in this assessment.¹⁷

¹⁶ Exemplary are the following:

Most financial and scientific observers concur that during the coming two decades, genetic engineering technologies will have a profit potential and social impact akin to the development of transistors and computers during the past 20 years. [PBC Brief at 2.] . . . Such a ruling [affirmance of the lower court decision herein] would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies. This, in turn, will lead to the rapid proliferation of genetic techniques in the areas of energy, agriculture, medicine, industrial processes and many other aspects of the nation's economic life. [PBC Brief at p. 3.] . . . [T]he flurry of research and development such patents will generate within the budding industry of genetic engineering are not in the public interest. [PBC Brief at 14.] . . . [G]ranting life form patents . . . will encourage industry to more rapidly develop genetic technologies. [PBC Brief at 17.] . . . [T]he granting of patents is sure to escalate the drive toward commercial application. [PBC Brief at 21.]

¹⁷ The final report on patent policy of President Carter's Advisory Committee on Industrial Innovation stated in reference to new life forms: "The availability of patents in this instance is certainly a stimulus to innovation, just as in the pharmaceutical fields, and seems justified for that reason." *Industrial Advisory Subcommittee Report on Patent Policy* in Advisory Committee on Industrial Innovation Final Report 145 (1979) [hereinafter cited as *Report on Patent Policy*] at 159. The report further states: "Unhindered by the threat of piracy, there will be stronger incentives to invest money in new and useful technology under the protection of the patent system." *Id.* In the same vein, the Director of the National Institutes of Health has stated: "The argument that commercial development based on patent protection has or will assure maximum benefits of these inventions to the public applies as well to the putative benefits of recombinant DNA inventions." Frederickson, *The Patenting Of Recombinant DNA Research Inventions Developed Under DHEW Support: An Analysis* by the Director, National Institutes of Health (November 1977) at 16. Indeed, National Institute of Medical Sciences head Ruth Kirschstein, testifying at a House Health, Education and Welfare Appropriation Subcommittee Budget Hearing on March 7, 1978,

It follows that genetic engineering research and development is precisely the type of technological innovation which the patent system was intended to promote and that the issuance of patents in this area will have precisely that effect. The degree to which this technology should be otherwise regulated is an issue wholly independent of the patentability question, as will be pointed out in greater detail in ensuing sections of this brief.

b. The absence of patents on living organisms will not preclude research or commercial exploitation in areas such as genetic engineering absent legislation by Congress, and will only limit public disclosure

From the inception of the patent system, patents have been regarded as performing the dual function of providing an incentive for technological innovation and providing a mechanism for early and widespread dissemination of technical information.¹⁸ Where patents are of doubtful validity or are unavailable, investors seek to minimize the not insubstantial risks of commercialization of new technologies by resort to trade secret protection. *See Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470 (1974). This is precisely the effect that the present uncertainty over the patentability of novel microorganisms is having in this burgeoning industry.

predicted that private industry will increase recombinant DNA research in the wake of the then recent CCPA ruling allowing new life forms to be patented. ²¹ The Blue Sheet, No. 10, RN-4 (March 8, 1978).

¹⁸ The White House Fact Sheet on the President's Industrial Innovation Initiatives issued October 31, 1979.

As recently reported in Newsweek, scientists-turned-entrepreneurs sometimes refuse to share their theories.¹⁹ An industry representative recently quoted in Business Week stated: "You keep your proprietary strains under lock and key."²⁰ The *Report on Patent Policy* notes that an argument favoring patenting new, useful and unobvious life forms "is that it provides an alternative to the less desirable avenue of trade secrets Maintenance of trade secrets also tends to stifle the free exchange of technology and hinders the progress of science by postponing the benefits to mankind of these technologies."²¹

The arbitrary exclusion of genetic engineering inventions from the patent system will not prevent the problems associated with continuing research, development and commercialization cited by PBC and Petitioner as militating in favor of that result. The only result of such exclusion will be that the public will suffer the further indignity of being subjected to potential risk from technology which is largely secret.

¹⁹ Newsweek quoted Stanford biochemist Paul Berg as follows: "No longer do you have this free flow of ideas. You go to scientific meetings and people whisper to each other about their company's products. It's like a secret society." Begley et al., *supra* note 5, at 53.

²⁰ Business Week, *supra* note 3, at 172.

²¹ *Report on Patent Policy*, *supra* note 17, at 159. Similarly, the Director of the National Institutes of Health observed: "Commentators from industry stated that patents expedite the disclosure of research results. Several noted that lack of patents would discourage the free flow of information because industry would seek to protect innovations through trade secrets." Fredrickson, *supra* note 17, at 6. The Director concluded: "There are no compelling economic, social, or moral reasons to distinguish these [recombinant DNA] inventions from others involving biological substances or processes that have been patented. . . ." *Id.* at 16.

Moreover, even if patents on new microorganisms *per se* are to be denied, there remains the concededly less desirable prospect that process patents can be obtained for some aspects of developing genetic engineering technologies.²² Indeed, as noted by the majority below, Chakrabarty's claims to a process for transferring plasmids and to an inoculated medium for the degradation of hydrocarbons have been allowed. 596 F.2d at 970-71. However, the relative ineffectiveness of these alternative forms of claims vis-a-vis claims to the basic product *per se* in protecting chemical and pharmaceutical inventions has long been recognized in the chemical patent law.²³ With this practical limitation in mind, it is seen that the arbitrary limitation of patents on novel microorganisms to claims other than those to the organism *per se* would have the wholly unsatisfactory effect of neither stopping innovation in the area nor fully encouraging its development and public disclosure. As noted at page 159 of the *Report on Patent Policy*: "If the progress of science is in the national interest, the term manufacture should be construed broadly, and patentability afforded to the useful bacteria resulting only from the efforts of man."

The foregoing economic realities merely serve to demonstrate and accentuate the legal characteristics of the patent grant. The grant, by its own terms, is simply the right to exclude others from practicing the invention. 35 U.S.C. § 154. It conveys no absolute right to the patentee to use the invention. *Application of Hartop*, 311 F.2d 249, 263 (C.C.P.A. 1962). Thus, as

²² Tullis, *supra* note 4, at 7.

²³ See, e.g., *Eli Lilly & Co. v. Generix Drug Sales, Inc.*, 460 F.2d 1096, 1103 (5th Cir. 1972); *Application of Papesch*, 315 F.2d 381, 391 (C.C.P.A. 1963).

is now the case with drugs, the patenting of a new microorganism will carry with it no right to commercialize that microorganism except as otherwise permitted by extant regulatory strictures.

c. The "sky-is-falling" arguments made against the patenting of living organisms could have been made against a multitude of inanimate technologies which have contributed heavily to this country's progress

Amicus PBC, and to a lesser extent Petitioner, liberally engage in what has been called "the doomsday scenarios of 'creative pessimism.'"²⁴ PBC is concerned with the lack of proven safety of genetic engineering techniques and seeks to impose on the Patent and Trademark Office the obligation to protect the public interest in this regard. However, as will soon be made apparent, controversiality has absolutely nothing to do with patentability. There are many technologies whose promotion is unquestionably in the public interest notwithstanding the presence of some degree of controversiality or risk in their practice. In 1977, nearly 5,000 people in the United States died of poisoning from exposure to chemical substances varying from antibiotics to petroleum products, yet PBC does not suggest that patents should not be granted on these concededly valuable materials. Also in 1977, 1,643 people died in air and space transportation accidents, yet PBC does not suggest that invention in this area should be unpatentable. Forty-nine thousand five hundred and ten people died in motor vehicle accidents in 1977, yet innovation in the area of automobile transportation is a high priority in

²⁴ Grobstein, *The Recombinant-DNA Debate*, in *Recombinant DNA* 131 (Scientific American, Inc. 1978) at 137.

energy conservation.²⁵ In short, arguments such as those here advanced by Petitioner and PBC predicated upon predicted calamities could have been advanced with equal force to arrest the development of any number of technologies, the overall social and economic value of which are now beyond question.

This point has not gone unnoticed in the genetic engineering debate. Grobstein notes that DNA techniques would not be the first technology to have potentially malevolent applications. "Explosives have such applications, but society does not completely ban them; it takes prudent precautions against their misuse."²⁶ Dr. J. D. Watson, Nobel laureate and codiscoverer of the structure of DNA, has noted:²⁷

Compared to almost any other object which starts with the letter D, DNA is very safe indeed. Far better to worry about daggers, or dynamite, or dogs, or dieldrin, or dioxin, or drunken drivers, than to draw up Rube Goldberg schemes on how our laboratory-made DNA will lead to the extinction of the human race.

It is for the Legislative and Executive Branches of government, not the Judicial Branch, to make the policy decisions with respect to the prudent precautions to be taken against the misuse of genetic engineering technologies. While the exact parameters of any regulatory scheme which may grow to surround these new technologies are presently unclear, it is presently clear

²⁵ National Safety Council, *Accident Facts 1979 Edition* (1979).

²⁶ Grobstein, *supra* note 24, at 140.

²⁷ Watson, *The Nobelist vs. the Film Star*, *The Washington Post*, May 14, 1978, at D1-2.

that the patent laws are not now and should not be part of that regulatory scheme.²⁸

As a practical matter, PBC has exaggerated the potential biohazards of genetic engineering technology. On June 23, 1976, in response to widespread debate on many of the issues raised by PBC and Petitioner, the NIH released guidelines to govern the conduct of NIH-supported research on recombinant DNA molecules.²⁹ In December 1978, NIH announced new, relaxed regulations in this area as a result of the failure of experiments designed to assess the potential hazards of DNA to demonstrate significant danger.³⁰ Indeed, a recent report in the press concerning worries cited by PBC and Petitioner was accompanied by the editorial comments that "those worries have eased" and that "much of the fear and controversy surrounding recombinant DNA research has dissipated."³¹

²⁸ A direct and compelling analogy is provided by the relationship between the patent laws and government regulation in the area of drugs. In *Hartop*, the CCPA rejected the notion that the Patent and Trademark Office was obliged to insure the safety and efficacy of patented drugs, noting: "The primary public duty, which the Patent Office is charged with performing under 35 U.S.C. §§ 101, 102 and 103, is to issue patents on applications which meet the statutory requirements." 311 F.2d at 261. Protection of the public from the use of unsafe and ineffective drugs is the responsibility of the Food and Drug Administration, not the Patent and Trademark Office. *Application of Anthony*, 414 F.2d 1383, 1395 (C.C.P.A. 1969).

²⁹ These guidelines specified varying degrees of containment procedures based upon the perceived degree of risk attending particular types of experimentation. See, e.g., Grobstein, *supra* note 24, at 141.

³⁰ *Business Week*, *supra* note 3, at 164.

³¹ *Business Week*, *supra* note 3, at 160, 164. See also Vossius, *Patentable Invention in the Field of Genetic Manipulations*, 1979 GRUR 579.

The conclusion is compelled that, while risk attends development of genetic engineering technologies, as it does development of many technologies, that risk is not as substantial as initially thought and certainly does not warrant rejection of the entire technology. In this regard, Nobel laureate J. D. Watson has described his own involvement in sounding the recombinant-DNA alarm as that of a "jackass" and has publicly stated his willingness to "go to jail" to "atone for the harm I've caused to others."³²

Much of PBC's rhetoric is a veiled policy argument that a technology conceded to be capable of widespread beneficial application should, nonetheless, be excluded from the protection of the patent system in vindication of a perceived social or ethical need to regard "aliveness" with an appropriate degree of awe and respect. A valuable lesson in this regard may be learned from the early experience with organic chemistry in which the very name of the field can be traced to the belief of Berzelius in 1807 that organic compounds could arise only through the operation of some "vital force" within the living cell.³³ While Berzelius' belief has since been shown to be unfounded, had that belief stood as a bar to patentability of inventions in

³² *Recombinant DNA and Genetic Experimentation* (Morgan and Whelan ed. 1979) at 236. Watson has stated his belief that DNA research is "much safer than many categories of work with disease-causing agents that the microbiologists have been carrying out for decades without significant harm to themselves, much less the public at large." Watson, *1978 Annual Report of Cold Spring Harbor Laboratory* (1978) at 6. See also *DNA Folly Continues*, *The New Republic*, January 13, 1979, at 12.

³³ See Fieser and Fieser, *Organic Chemistry* 3 (3d ed. 1956).

the area of organic chemistry, the development of that extremely useful art would have been greatly impeded.

If, because of overriding social or ethical questions such as concern for the public safety, national security, or public morals, the policy-making bodies of our government conclude that it is not in the public interest to grant patents in an area of the useful arts, it is incumbent upon those bodies, as it has been in the past, to exclude legislatively that technology from the scope of patent protection. Congress clearly did so in 1946 and 1954 by excluding certain innovations in the field of atomic energy from the scope of the patent laws.³⁴ The Congress was asked to act similarly in 1902 with respect to medical inventions but refused to do so.³⁵ It is manifestly more sound for Congress to act in those few areas where the patenting of new technologies will present social problems than to require the progenitor of every technological innovation to beseech Congress to enumerate specifically his technology in the statutes of the United States. Several foreign countries have enacted such exclusionary legislation respecting the patentability of higher life forms. The

³⁴ On August 1, 1946, Congress enacted the Atomic Energy Act of 1946, 60 Stat. 768, which excluded the production of fissionable material and the military utilization of atomic energy from the scope of the patent laws. On August 30, 1954, Congress enacted the Atomic Energy Act of 1954, 68 Stat. 943, relaxing but not eliminating the proscriptions of the 1946 Act.

³⁵ H.R. 12451, 57th Cong., March 12, 1902, *A Bill Amending the Statutes Relating to Patents, Relieving Medical and Dental Practitioners from Unjust Burdens Imposed by Patentees Holding Patents Concerning Methods and Devices for Treating Human Disease, Ailments, and Disabilities*.

new patent laws of Great Britain and West Germany are examples.³⁶

3. The potential patenting of higher forms of life is not before this Court in this case and need not be decided in order to resolve the issues presented by the Chakrabarty invention

The essence of the argument advanced by *Amicus* PBC is that if patents are allowed on microorganisms, it will be impossible to "draw the line" between lower and higher forms of life up to and including human clones. This case, being one of first impression, requires not the drawing of any line but merely the determination of whether a man-made microorganism which is new, useful and nonobvious must be excluded from patent protection merely because it is "alive." The judiciary does not usually draw lines prospectively, but instead decides concrete, present controversies. When a concrete controversy presenting more difficult patentability questions is presented, a line may have to be drawn, and that decision may not be an easy one to reach. However, the fact that a controversy is difficult to decide is no reason not to decide it.

This Court has in the past grappled with extraordinarily difficult legal controversies, many involving the mystical qualities of life here argued by PBC, and has, where necessary, drawn difficult lines. A classic example is this Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973), where the right of a woman and her physician to terminate a pregnancy during the first trimester was sustained. This Court wisely declined

³⁶ It is to be noted that these foreign laws did not so exclude microorganism inventions and that microorganisms *per se* remain patentable in such countries. See § 3, *infra*.

to base that legal decision on the widely varying philosophical and theological views urged upon it as to when human life began, and instead based its decision on a more practical analysis of the public and private interests involved. Similar analysis is called for in the instant case.

The all-or-nothing argument of Petitioner and PBC is unsound for several practical reasons. In the first place, the patentability question will only be presented with respect to organisms which otherwise meet the existing statutory requirements for patentability. In this regard, it has long been recognized that the disclosure requirements now embodied in 35 U.S.C. § 112 are so stringent as to preclude as a practical matter the preparation of a complying description for even an asexually reproduced complex organism such as a rose. See *Application of LeGrice*, 301 F.2d 929 (C.C.P.A. 1962). Thus, except to the extent that certain complex plants are exempted from the disclosure requirement of 35 U.S.C. § 112 by special legislation, as they are under 35 U.S.C. § 162,³⁷ those organisms cannot be the subjects of valid United States patents. Petitioner seemingly concedes that the disclosure requirements will present insurmountable obstacles to the patenting of higher forms of life by noting: "[T]he reproductive ability of living things, and the small likelihood that even the most exact description of the method by which the originator developed his claimed invention will

³⁷ 35 U.S.C. § 162 provides in pertinent part:

No plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible.

This provision was part of the Plant Patent Act of 1930, to be discussed, *infra*.

permit its duplication, mean that living things do not fit easily within the general patent statute." Pet. Brief at 16, n.14.

With respect to a very narrow class of living inventions, namely microorganisms, mechanisms have been developed and judicially sanctioned for complying with the exacting disclosure requirements of the general patent law. *Application of Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970), sanctioned the placement of a novel microorganism employed in a microbiological invention in a national depository coupled with reference to the location of that deposit in the patent application as a means for complying with the requirements of § 112. Manifestly, unlike microorganisms which can be continuously cultured, higher forms of life present substantial problems in terms of indefinite maintenance on deposit and identical reproduction from the deposited specimen. Thus, there is little danger that issues involving the patentability of higher forms of life will arise in the absence of Congressional action akin to the 1930 Plant Patent Act reducing the disclosure requirements for these inventions.

Other sections of the existing patent law may also impede patenting of some of the more bizarre examples cited by PBC. For example, it is not inconceivable that a clone, an exact genetic duplicate of an existing organism, will be regarded as unpatentable for failure to comply with the novelty requirements expressed in the patent laws.

The fears of PBC are greatly overstated.

From the foregoing, it is apparent that, if a line must be drawn, it may easily be drawn between the mindless, soulless microorganism involved in *Chak-*

rabarty (as well as *Bergy*) and higher forms of life. As noted by the CCPA majority below, microorganisms such as that are more akin to inanimate tools of chemistry than they are to horses, honey bees and the like. Indeed, these inventions have recently been characterized as "Factories Too Tiny to See."³⁸

There seems to be technical support for such a distinction. For example, it has been noted that "[m]icro-organisms can be distinguished from plants and animals by their unicellularity or, in the case of multicellular forms, by their low level of tissue differentiation,"³⁹ and this distinction has been adopted in the patent laws of various European countries.⁴⁰

³⁸ Mathews, *Factories Too Tiny to See*, The Washington Post, January 23, 1980, at A-23.

³⁹ Byrne, *Patents on Life*, EIPR November 1979, 297 at 299. See also Grobstein, *supra* note 24, at 137 distinguishing between prokaryotic organisms such as bacteria and eukaryotic organisms such as man on the basis of the location and complexity of chromosomes.

⁴⁰ Byrne, *supra* note 39, at 299. The structure of the British Patents Act 1977 is generally to authorize issuance of patents for any invention which is new, inventive and capable of industrial application and, in subsequent sections of the act, to exclude from the general class of inventions patentable those which present particular social problems. Section 1(3) is such a section, and reads in pertinent part:

(3) A patent shall not be granted—

(b) For any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

The British law represents enabling legislation carrying into effect the provisions of Article 53(b) of the European Patent Convention, which has been ratified by at least ten European countries, and in accordance with which microorganisms themselves but not higher life forms are patentable. See Vossius, *Patent Protection for Biological Inventions—Review of Recent Case Law in EEC Countries*, EIPR October 1979, 278.

European governments are actively promoting genetic engineering research and some U.S. investment and research activity is moving overseas. The potential exists, therefore, for the U.S. to lose its hold on this technology, and this potential should not be lightly dismissed in considering the practical impact of the issue presented by this case."

4. **Petitioner's argument based on the practical success or failure of the patent acts covering plants is irrelevant to the issues in this case and is based on faulty factual assumptions**

Amicus PBC argues by analogy that permitting the patenting of life forms will have the same deleterious effect on the animal gene pool that the various plant patent laws are alleged to have had on the plant gene pool. In this regard, PBC states (1) that a direct result of plant patent legislation has been the elimination of thousands of useful varieties of plants from the planetary gene pool; (2) that as patentable plants have been widely propagated, nonpatentable varieties have been eliminated resulting in disease and pest-susceptible crops; and (3) that plant patents have made plant breeding such a lucrative endeavor that ownership of the world's basic food supply is increasingly being concentrated within a small number of large, multinational corporations. PBC Brief at 6-13.

Initially, it must be noted that there is no comparison between the magnitude of the plant gene pool and that of the microorganism pool. Plants, by their size, complexity of structure and ability to grow only in

⁴¹ *Business Week*, *supra* note 3, at 164. See also D. Dickson, *Recombinant DNA Research: Private Actions Raise Public Eyebrows*, 278 *Nature*, 494, 495 (April 1979), reporting the willingness of certain industrial elements to locate in the country offering the most acceptable environment for research.

various zones, are finite in number. Prokaryotes (unicellular microorganisms), by comparison, are simple in structure and reproduce everywhere on this earth in virtually infinite numbers. Accordingly, it is reasonable to assume that genetic engineering research will not reduce the gene pool relating to microorganisms but, if anything, will add to it.

Moreover, the PBC argument is based on faulty factual assumptions. Although germplasm (genetic material) *conservation* is a relatively recent phenomenon, the *loss* of germplasm is something that has been occurring ever since man first cultivated crops. Today, scientists aware of the problem have set up germplasm preservation centers.⁴² While it is acknowledged that a problem exists in conserving all the germplasm extant on the planet, this is a problem that precedes by hundreds of years the passage of the plant protection laws and which, with the attention generated by the passage of those laws, has been recognized and is being rectified. Surely, a dynamic plant-breeding industry—in both the private and public sectors—which has as one of its functions the task of maintaining genetic stocks, is one of the best safeguards against "genetic wipeout."

With regard to the PBC allegation of widespread monoculturing and the resultant disease and pest-

⁴² The U.S.D.A. maintains such a center at Fort Collins, Colorado, for preservation and distribution of samples of all seeds sent to the Patent and Trademark Office and to the U.S.D.A. The U.S.D.A. also collects wild seeds and maintains regional preservation centers in seven United States cities. There are also seven International Research Centers acting as repositories for seed which is made freely available to any country and to any breeder. J. M. Poehlman, *Breeding Field Crops*, (2d ed. 1979) at 109-112.

susceptible crops, it is true that there was an extensive corn blight in the U.S. in 1970, resulting in part from genetic limitations of a widely used corn seed. However, the very seed companies which supplied the corn seed in 1970 were able to obtain germplasm from the regional centers and were able to correct the deficiency by the planting of the 1971 crop.⁴³

With respect to the effect of prior legislation on the major food crops, it must be remembered that the Plant Patent Act of 1930 applies only to asexually reproduced plants, which include very few food crops. Thus, although beans, peas and lettuce theoretically might be subject to patents, they in fact are not. It is only since 1970 that sexually reproduced plants, which include most major food crop plants, have been certified. The effect of the 1970 Act, far from reducing the number of varieties available to the American public, has increased them.⁴⁴ The result of the passage of the 1970 law has been to foster technology and to increase the number of hearty varieties of crop seed available to the American farmer.⁴⁵

⁴³ It should also be noted that the first certificates under the Plant Variety Protection Act were issued in 1972, so the effects of that act cannot be said to have contributed to the corn blight.

⁴⁴ For example, there were as many new varieties of wheat developed in the seven years following passage of the Plant Variety Protection Act as had been developed in the previous seventeen years. *Hearings on H.R. 2844 Before the House Agriculture Subcommittee on Department Investigations, Oversight and Research*, July 19, 1979 (Statement of Commissioner Leese, Office of Plant Variety Protection). Similarly, while there were six companies doing work with soybean breeding before 1970 there are presently 25. White, *Plant Variety Protection Update*, Proceedings of the Sixth Soybean Seed Research Conference (1976) at 33, 37. See also Poehlman, *supra* note 42, at 448-49.

⁴⁵ This is exactly the result foreseen by the House Agriculture Committee in its report on the Plant Variety Protection Act. The

Finally, *Amicus* PBC's contention that the Plant Variety Protection Act has lead to a monopolization of the world's germplasm through patents is similarly mistaken. In the decade since the passage of that Act, the number of seed companies, especially in soybeans, wheat and cereal grains has increased.⁴⁶ Some acquisition of small companies by petrochemical companies, multinational and otherwise, has taken place, and these companies may own a large percentage of issued plant patents, but this by no means proves control of any given crop's germplasm.⁴⁷ The mere number of patents

Committee noted that the seed industry in Western Europe and especially England, far from withering, showed "signs of great new vitality" after passage of the patent act. The House Report further stated:

Legal protection for plant varieties will give American farmers the choice of more and better varieties. . . . Soybeans provide a good example of a crop that could and would be more productive as a result of the more and better varieties which would be available as a result of legal protection for plant varieties. Other major U.S. crops, like cotton, wheat, barley, oats, and rice, for example, now largely ignored by the private researchers, would almost certainly benefit greatly from the impact of a competitive, private plant breeding effort. . . .

H.Rep. No. 91-1605, 91st Cong., 2d Sess. (1970).

⁴⁶ *Hearings on H.R. 2844, supra* note 44 (Statement of Harold Loden, Executive Director of the American Seed Trade Association). Membership in ASTA has increased 25% in the last five years. See also statement of Leese, *supra* note 44.

⁴⁷ For example, *Amicus* PBC cites Ciba-Geigy as one of those companies controlling plant patents through Funk Seeds International and Stewart Seeds, and hence the germplasm of the plants covered. In reality, Funk has only one certificate and that is on a soybean variety not currently on the market and not likely to be marketed. Stewart Seeds is a Canadian seed company not within the control of Ciba-Geigy (U.S.).

In a similar vein, Monsanto, another giant cited by *Amicus* PBC as a monopolizer of plant patents has no seed companies.

owned by individual companies or groups of companies proves nothing with respect to market control. In all areas of technological innovation, the largest numbers of patents are usually held by corporate entities, and there is no way to determine from the numbers of patents held which are the important and controlling patents."

In the seed field, ownership of plant certificates does not dictate control of the sale of seed. In this regard, it is noted that U.S. seed companies have traditionally been small, family firms without the capital to invest in long-term research projects leading to new varieties. Since the seeds sold by these companies are not usually certified, there is no way to account for their share of the market.

Since 1970, 980 applications on 57 distinct crops have been received by the Plant Variety Protection Office. Of these, only 197, or roughly 1/5, were from the six largest U.S. seed companies. One hundred seven applications were from experimental stations and the rest, 676, were from private breeders of all sizes." This diversity belies the contention of *Amicus* PBC that plant certification has encouraged undue concentration

Farmer's Hybrid, cited in Cary Fowler's testimony (PBC Brief at 12, note 10), is a pig hybridization company.

⁴⁸ *Report on Patent Policy*, *supra* note 17, at 152 n.13, 166.

⁴⁹ See Statement of Leese, *supra* note 44. A perusal of the Indices to the Official Journal of the Plant Variety Protection Office supports this diversity. In 1978, for example, 90 certificates were issued to more than 50 seed companies. Twenty certificates were issued on beans, peas and lettuce, the crops named by the PBC as "controlled," to eleven different companies, including an individual seedsman.

of ownership of seed companies to the detriment of the public.

B. The Holding Below in *Chakrabarty* Is Totally Compatible With an Almost 200-Year Old Statutory Scheme and the Historical Application of the Patent Laws

1. Contrary to *Deepsouth*, this is not an extension of patent laws

Petitioner relies heavily on this Court's statement in *Flook* that it "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress," 437 U.S. at 596, which in turn relied on *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518 (1972). In its opinion, 596 F.2d at 966-967, the CCPA easily distinguished *Deepsouth* on the basis of the legal issue involved therein (infringement), the language of 35 U.S.C. § 271 and the large body of judicial precedent construing Section 271, the latter having been characterized by this Court as "unassailable absent congressional recasting of the statute." 406 U.S. at 528. Since whether subject matter is excluded from Section 101 of the patent statute merely by virtue of being "alive" is, according to both Petitioner (Pet. Brief at 13) and the CCPA, an issue of "first impression," there is no "unassailable" judicial construction of the statute which one must look to Congress to overrule. Accordingly, the issue in this case is not whether there is to be *extension* of a statutory privilege of the sort contemplated in *Deepsouth*, but instead whether the *Chakrabarty* invention qualifies for an *existing* statutory privilege.

2. The statutory scheme since 1790 has contemplated patenting of new and unforeseen technologies

Petitioner seeks to glean support from *Flook* for the proposition that the impetus for extension of the patent laws to new technologies must come from Congress. Despite the sharp differences reflected in the majority and dissenting opinions below, the CCPA *unanimously* rejected this proposition. 596 F.2d at 973. Indeed, any such theory would be wholly inconsistent with the statutory scheme and the historical application of the patent laws.

Scarcely two and one-half years after the signing of the Constitution, the first Congress enacted the Patent Act of 1790.⁵⁰ Section 1 of the Act provided for patents to be issued to persons who have invented or discovered "any useful art, manufacture, engine machine, or device, or any improvement therein not before known or used" Section 2 of the Act of 1790 required further that the grantee deliver a written specification containing a description of the invention which would enable one "skilled in the art of manufacture, whereof it is a branch, *or wherewith it may be nearest connected* [emphasis added]" to make and use the invention. One could not ask for a clearer manifestation of the perception of the first Congress that the patent laws were intended to encompass innovation in areas not pertaining to *existing* arts than the plain meaning of the first description requirement. Moreover, implicit in Section 1 of the Act is the presumption that "any useful art," for example, should include more than mere improvements on existing arts, since the additional provision for "improvement[s]"

⁵⁰ 1 Stat. 109, April 10, 1790.

therein" would otherwise be wholly superfluous. Upon construing Sections 1 and 2 of the Patent Act of 1790 together, the conclusion is compelled that the categories of patentable subject matter defined in that Act included altogether new and unforeseen technologies. Parallel statutory requirements survive to this day in 35 U.S.C. §§ 101 and 112.

3. The patent laws historically have been applied to new technologies as they developed, including those related to living organisms

That the patent laws historically have been extended to new technologies as they have developed is apparent from a chronological review. With respect to historical development of the statutory language, it is noted that the United States patent laws were amended shortly after enactment of the first patent act by the Patent Act of 1793.⁵¹ This Act provided for patents to be granted to persons who invented "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter" The disclosure requirements were carried over in Section 3 of the Act of 1793. The resemblance of these two sections to the present law is obvious, and this similarity prevailed through amendments to the substantive patent law which Congress had occasion to make in 1836, 1870, 1874, 1930, and 1952. The nature of the technological developments accepted within the patent system during the intervals between congressional reexamination of the statute belies any conclu-

⁵¹ 1 Stat. 318, February 21, 1793.

sion that new technologies were not regarded as falling within the statutory language.⁵²

Two examples serve to illustrate the point. In 1840, a patent was issued to Samuel Morse for an invention relating to "Telegraph Signs,"⁵³ and the validity of the first seven claims of that patent was upheld by this Court in the landmark case of *O'Reilly v. Morse*, 56 U.S. (15 How.) 61 (1853). Nearly 60 years later, in 1897, Guglielmo Marconi received a patent for "New and Useful Improvements in Transmitting Electric Impulses and Signals and in the Apparatus Thereof"⁵⁴—the forerunner of the radio. Congress itself has spoken on the lack of foreseeability of such new technologies in the legislative history of the Plant Patent Act of 1930, where it characterized telegraphic communication and radio communication as "matters beyond the wildest dreams of the framers of the Constitution."⁵⁵ One would think that statutory language which had allowed the issuance of the Morse and Marconi patents on telegraphy and radio, and which allowed this Court to sustain as a patentable invention Morse's telegraph when properly claimed, would be acknowledged as subsuming within its scope wholly unforeseen and new technologies in view of this express Congressional statement.

⁵² This point is developed extensively by counsel for Amicus PMA in Dunner et al., *The Patentability of Life Forms, New Technologies and Other Flocks of Nature*, 7 A.P.L.A. Quart. J. 190 (1979) at 198-203.

⁵³ U.S. Patent No. 1,647, issued June 20, 1840.

⁵⁴ U.S. Patent No. 586,193, issued July 13, 1897.

⁵⁵ S.Rep.No. 315, 71st Cong., 2d Sess. (1930) at 8.

Microorganisms have not been strangers to the patent system and actually formed the subject matter of a number of United States patents issued since the 1930's.⁵⁶ Indeed, in 1873, a patent was granted to Louis Pasteur for "Improvements in the Manufacture and Preservation of Beer and in the Treatment of Yeast and Wort, Together with Apparatus for the Same."⁵⁷ For purposes of our present inquiry, it is interesting to note that claim 2 of the Pasteur patent called for "Yeast, free from organic germs of disease, as an article of manufacture,"⁵⁸ or in other words, a biologically pure culture of a microorganism. Moreover, it was a microbiological invention which was considered by the Supreme Court in *Funk*.

From the foregoing, it is apparent that the patent statutes, in practical application, have throughout the

⁵⁶ Exemplary are the patents collected in Daus et al., *Microbiological Plant Patents*, 10 IDEA 87 (1966) and listed in the CCPA majority opinion, 596 F.2d at 985-86.

⁵⁷ U.S. Patent No. 141,072, issued July 22, 1873.

⁵⁸ Petitioner notes that a commentator in 1937 questioned the validity of this claim of the Pasteur patent. Federico, *Louis Pasteur's Patents*, 86 Science 327 (1937). It is noted that the authority cited for that position was *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1930), which, as pointed out in § A.1, *supra*, does nor bar the patentability of such purified microorganism cultures.

Petitioner, at pages 39-40 of its brief, also challenges the precedential value of the prior patents issued on microorganisms noted by the lower court, 596 F.2d 985-86. It is contended that the cited examples are "aberrant." It must be noted however, that the patents cataloged in the majority opinion are said to be typical and by no means exhaustive. Moreover, most of them were issued *after* and notwithstanding the publication of the foregoing remarks of P. J. Federico. Petitioner cites no evidence of aberration in the grants of these patents, which must be presumed to have been validly issued (35 U.S.C. § 282), other than Petitioner's present opinion on the patentability of microorganisms which finds no basis in published policy prior to the present controversy.

history of the system routinely been construed as covering technological innovation, both animate and inanimate, wholly unforeseen by the founding fathers in the 18th Century or even by legislators in 1952. Accordingly, there is no warrant for any construction of the *Flook* dictum relating to "new technologies" which would bar technological innovation from the subject matter susceptible of being patented simply because it is innovation not foreseen by the drafters of the Constitution or the various patent statutes.⁵⁹

4. Applying the patent laws to new and unforeseen technologies best achieves the constitutional purpose of promoting the useful arts

The constitutional purpose of the patent system is to promote the progress of the useful arts. If one believes in the patent system, one would want to use the patent grant as a tool to encourage invention and innovation whenever and wherever it appeared capable of achieving that purpose. Of course, where Congress or this Court has clearly spoken to the contrary, the patent option will be unavailable. But where neither has done so, which we submit is the case here, there is

⁵⁹ Notwithstanding the foregoing, Petitioner contends that the statutory terms "manufacture" and "composition of matter" are "obscure" and "hardly define themselves" and must be construed in light of remotely related legislation (Pet. Brief at 30). In point of fact, however, historical perspective shows the meaning of these terms to be quite clear, albeit very broad. Petitioner confuses breadth with indefiniteness. Simply stated, all manner of materials brought into existence by the hand of man have been regarded as manufactures, whether foreseeable or unforeseeable. It is noted in this regard that resort to legislative history, such as that of the Patent Act of 1930 so heavily relied upon by Petitioner, is unnecessary when the statutory language is unambiguous, as it is here in light of its historical application. *United States v. Oregon*, 366 U.S. 643, 648 (1961).

no reason to go out of the way to create artificial impediments to the patent-granting process. As Judge Markey so aptly stated in his original concurring opinion in *Chakrabarty*:⁶⁰

As with Fulton's steamboat "folly" and Bell's telephone "toy," new technologies have historically encountered resistance. But if our patent laws are to achieve their objective, extra-legal efforts to restrict wholly new technologies to the technological parameters of the past must be eschewed. Administrative difficulties, in finding and training Patent and Trademark Office examiners in new technologies, should not frustrate the constitutional and statutory intent of encouraging invention disclosures, whether those disclosures be in familiar arts or in areas on the forefront of science and technology.

C. Contrary to Petitioner's View, It Was Not the General Understanding Prior to the Decision Below That Legislation Was Needed if the Patent Laws Were to Be Applied to Microorganisms

Petitioner contends that the decision below was a departure from the general understanding that patent coverage was not available for microorganisms absent legislation (Pet. Brief at 13). Petitioner's argument in this regard is multi-faceted, relying on prior judicial precedent, pronouncements of the organized bar and statements of commentators.

It is stated that the only judicial pronouncements on the subject suggest living things are not themselves patentable. *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F.2d 400 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933), and *Application of Mancy*, 499 F.2d 1289 (C.C.P.A. 1974)

⁶⁰ 571 F.2d at 44.

are cited by Petitioner in support of this proposition. Such reliance on these decisions is necessarily blunted by Petitioner's concession in the paragraph containing these citations that the question involved in this case "is an issue of first impression."

One of the reasons this is a case of first impression is that *Guaranty Trust*, in holding a microbiological process patentable, expressly demurred on the question of the patentability of bacteria per se: "Were the patent for bacteria per se, a different situation would be presented." 54 F.2d at 410. Similarly, there was an express reservation of decision on the issue here presented in *Mancy*: "[A]ppellants . . . would, we presume (without deciding), be unable to obtain such a [micro-organism] claim" 499 F.2d at 1294. The *Mancy* court's presumption was based on the not uncommon perception of such microorganisms being "products of nature," a point not at issue in this case.⁶¹

Petitioner also suggests, through citation of excerpts from reports of various bar associations, that the organized bar regarded legislation as necessary to bring microorganisms within the ambit of the existing patent law. Far from supporting Petitioner's theory,⁶² the

⁶¹ While Petitioner goes to great pains to demonstrate that what was involved in *Mancy* was in fact no more a product of nature than the purified microorganism of Bergy, the uncontroverted fact is that the *Mancy* court, rightly or wrongly, expressly presumed the microorganism there involved to be a product of nature.

⁶² For example, Resolution 22 of the American Bar Association Patent, Trademark and Copyright Law Section (ABA Pat. Sec.) passed in 1966, regardless of how entitled, stated support for the "application of the principles of the patent system to all . . . microorganisms." 1966 ABA Pat. Sec. Summary of Proceedings at 84, emphasis added. That "extension" of the patent laws is not necessarily entailed in such "application" of them to microbiology is manifest from the accompanying Report of Committee 108 on Patent System Policy Planning, where it is stated: "There

reports of the organized bar suggest the perception that microorganisms were patentable under existing law.

is no logical reason why asexually reproduced plants and microorganisms should be covered by patents as at present, where sexually reproduced ones are not covered by patents" 1966 ABA Pat. Sec. Committee Reports at 77, emphasis added.

The problems perceived in this area were problems of description, as demonstrated by Resolution 11 adopted by the full ABA in 1969 approving the deposit of novel microorganisms in public depositories as a means of complying with the disclosure requirements of the patent laws. This resolution was seen as eliminating uncertainty in the application of existing law to microorganisms: "The proposed legislation would take nothing away from the existing statute, 35 U.S.C. § 112, but rather would codify and settle Patent Office practice in this area." 1969 ABA Pat. Sec. Committee Reports, Report of Committee 101 on Patent Law Revision at 14. In this regard, the legislation supported by the ABA referred to at page 29, n.35 of Petitioner's brief as being "with respect to patent protection for micro-organisms" actually related to elimination of these description difficulties.

Microorganisms were also mentioned from time to time by various committees and subcommittees dealing with plant patent legislation. Exemplary is the Report of Subcommittee E of Committee 103 in the 1969 ABA Pat. Sec. Committee Reports quoted by Petitioner at page 14 of its brief. By the very terms of the Committee Report, the quoted remarks were speculative since the Committee had "not conducted a study in depth of the microbiological area with relation to patents." *Id.* at 123.

Petitioner also relies (Pet. Brief at 14, n.12) on a 1976 resolution of Committee 111, Plant Patents and Plant Variety Certificates, suggesting revision of existing plant patent provisions to include microorganisms. Petitioner fails, however, to note that the accompanying 1976 ABA Pat. Sec. Summary of Proceedings at 95 suggests that the provision "was removing a disability rather than creating a new right [emphasis added]."

In stark contradiction to the position urged by Petitioner, the very committee responsible for original Resolution 22 in 1966 saw no apparent inconsistency in 1978 in adopting Resolutions 30, 31 and 32 favoring construction of the existing patent laws so as to include microorganisms within their scope. 1978 ABA Pat. Sec. Summary of Proceedings at 64-67.

Petitioner's reliance on literature references to the desirability of additional legislation is also misplaced. Examination of the references cited at p. 15, n.13 of Petitioner's brief merely confirms the obvious—that legislation beyond the Plant Patent Act of 1930 would be required to allow patenting of various other kinds of *plants, animals and their products*. Nothing is said of microorganisms save the passing reference to "yeast" in Dienner, *Patents for Biological Specimens and Products*, 35 J. Pat. Off. Soc'y. 286, 290 (1953). That lone reference is in the context of an arguendo assumption that "national legislations could be construed *as they stand*, or amended as desired, to cover biological products and specimens [emphasis added]."

D. Congress Did Not Intend to Exclude Microorganisms From the Scope of 35 U.S.C. § 101

1. Petitioner's position that the Plant Patent Act and Plant Variety Protection Act preclude construction of 35 U.S.C. § 101 to cover microorganisms is based on fallacious assumptions and unduly expansive interpretations of the legislative history

Petitioner contends in essence that all living things are excluded from patentable subject matter under 35 U.S.C. § 101 because patents for certain kinds of *plants* have been the subject of subsequent legislation. Even this simple statement of Petitioner's position reveals two of its major flaws. In the first place, Petitioner consistently characterizes considered statements made in reference to specific "plants" or "animals" as supporting identical propositions with respect to the broader class of "living things."⁴³ Petitioner consist-

⁴³ Merely by way of example, Petitioner cites a remark of Representative Purnell relating to "new forms of *plant or animal* life (emphasis added)" at page 26 of its brief and extrapolates

ently engages in the patently fallacious syllogism that (1) certain plants and animals were unpatentable prior to 1930, (2) plants and animals are "living things" and, therefore, (3) all "living things" were accordingly unpatentable prior to 1930.

Plants, in the common sense of the word, were not patentable before 1930 because they could not be described with the particularity required by the patent statutes.⁴⁴ There was the parallel concern in 1930 that plants were unpatentable because they were "products of nature." The legislation in 1930 eliminated the dis-

it to a conclusion relating to "patentability for living things." That same conclusion is also said to be supported by a similarly unwarranted extrapolation of a remark of Representative Stafford relating to the unpatentability of "rare species of cattle or chickens." Moreover, at page 15, n.13 of its brief, Petitioner cites Glascock and Stringham, *Patent Soliciting and Examining* 591 (1934) and R. Allyn, *The First Plant Patents* 10 (1934) as examples of experts who thought that "without additional legislation no patents could issue for *living things*." In point of fact, however, Glascock and Stringham referred only to "plants" and "novel types of animal life" while the cited Allyn page merely suggests further encouragement for "animal breeders."

⁴⁴ In this regard, note *Application of LeGrice*, 301 F.2d 929, 944 (C.C.P.A. 1962), where the court noted: "[T]here is no possibility of producing the plant *from a disclosure* as 35 U.S.C. § 112 contemplates." The court went on to note: "The descriptions of the new roses in the instant publication [footnote deleted] . . . are incapable of placing these roses in the public domain by their descriptions when interpreted in the light of the knowledge now possessed by plant breeders." *Id.* Note also the following from Rossman, *The Preparation and Prosecution of Plant Patent Applications*, 17 J. Pat. Off. Soc'y. 632, 638 (1935):

It may be interesting to note that botanists long ago gave up the attempt to differentiate plants by verbal description and even drawings and photographs. They rely only upon actual examination of the plants. The patentability of a new distinct variety thus necessarily rests upon the possibility of so describing and illustrating it that it can be identified or distinguished from other closely related forms with reasonable accuracy.

closure impediment and clarified the "product of nature" point. It cannot seriously be contended that this clarifying legislation compels the conclusion that some other type of "living thing," *e.g.*, microorganisms, to which the description requirement and "product of nature" impediments are not applicable, would not have been patentable under existing law.

The second flaw in Petitioner's position is that it constitutes an *ex post facto* construction of statutory language dating back to 1793 on the basis of opinions expressed by Congress more than 150 years later. Such after-the-fact opinions are of little legal value even if clearly expressed, as they certainly are not in this case.

a. The Plant Patent Act and the Plant Variety Protection Act had nothing to do with microorganisms

As pointed out in *Application of Arzberger*, 112 F.2d 834 (C.C.P.A. 1940), which held that microorganisms were not intended by Congress to be patentable under the Plant Patent Act of 1930, while the scientific definition of plants at the time of the 1930 Act arguably may have included bacteria, the nonscientific common language definition surely did not. According to *Arzberger*, the word "bacteria" was not mentioned in the House and Senate reports accompanying the bills leading to the 1930 Act, confirming the view "that Congress, in the use of the word 'plant', was speaking 'in the common language of the people,' and did not use the word in its strict, scientific sense." 112 F.2d at 838.

In short, Congress, in enacting the Plant Patent Act of 1930 for the purpose of affording "agriculture so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given

industry," and in removing the "existing discrimination between plant developers and industrial inventors,"⁶⁵ was not suggesting or even remotely intimating that bacteria had not previously been covered by the patent laws, but only that "plants" in their commonly understood form were not so covered. Thus, the legislative history of the 1930 Act is, at best, neutral on the subject of the patentability of bacteria (microorganisms). Since Congress gave absolutely no thought to the patentability of bacteria, or whether or not they were covered by the existing patent laws, it can hardly be concluded that anything Congress did in 1930 bears on that issue.

Little more is added to the foregoing by the Plant Variety Protection Act. Petitioner notes that the subject matter for which Certificates of Plant Variety Protection can be issued specifically excludes bacteria and fungi. The legislative history of the Act is strangely silent on the reasons for the exclusion of bacteria and fungi. However, the protection intended is characterized in the Report of the House Agriculture Committee⁶⁶ as "similar" to the protection afforded asexually reproduced varieties through plant patents. As above noted, the manifest limitation of

⁶⁵ S. Rep. No. 315, 71st Cong., 2d Sess. (1930) at 1.

⁶⁶ H. Rep. No. 71-1605, 91st Cong. (1970). Petitioner, at pages 27-30 of its brief, makes much of the fact that Congress in 1970 regarded additional legislation as necessary to protect sexually reproduced plants. However, the impediments to the patenting of complex plant life, such as the inability to describe plants, apply to all such plants, not just the asexually reproduced plants for which the impediments were removed in 1930. Since the earlier legislation was restricted to asexually reproduced plants, there is no great significance to the subsequent passage of parallel legislation to convey the benefits of patent-type protection to the previously excluded class.

Congressional intention in enacting the Plant Patent Act to plants in the ordinary sense of the word had been judicially recognized for 30 years before passage of the Plant Variety Protection Act, and the express limitation of the latter to plants in the ordinary sense of the term can be regarded as nothing more than a desire to parallel the existing legislation. It does not, therefore, manifest any greater consideration by Congress of the issue presented by these cases than occurred in 1930.

b. The views of a subsequent Congress are of little value in determining the intent of a prior Congress.

As the majority opinion below aptly noted, the remarks of a subsequent Congress cannot safely be used to ascribe to a preceding Congress an intent which the latter did not itself state. 596 F.2d at 978.⁶⁷ Petitioner seeks to distinguish the situation in *Chakrabarty* by noting that the patent laws had been "codified" in 1952 so that yet a third Congress had spoken on the topic (Pet. Brief at 30-31).

Even if it were assumed that this third Congress tacitly endorsed all the remarks of the second Congress, an assumption not warranted by the cited legislative history, the net effect remains that of a later Congress opining on the intent of an earlier Congress—still a wholly unreliable indication as to the construction of the original act. Moreover, even if the 1952 codification represented adoption of the views of the

⁶⁷ Petitioner challenges (Pet. Brief at 30, n.36) the lower court's reliance on *United States v. Price*, 361 U.S. 304 (1960), as support for this proposition. Whatever else *Price* may stand for, it unequivocally states as an *independent* ground for decision: "Moreover, the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *Id.* at 313.

1930 Congress, those adopted views were no more compelling in 1952 than they were in 1930 for the reasons noted herein.

2. Collateral elements of the legislative history of the Plant Patent Act do not establish a Congressional intention to exclude microorganisms from the scope of the patent laws

Petitioner also relies on several other collateral elements of the Plant Patent Act legislative history, primarily a remark made by Secretary of Agriculture, Arthur M. Hyde, in a letter appended to the report of the Senate Committee on Patents,⁶⁸ wherein it is stated:

This purpose [to encourage improvement of some kinds of plants] is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.

The report to which the letter is appended twice quotes Secretary Hyde, once as to the desirability of the proposed legislation⁶⁹ to agriculture and the public and once for an assurance of cooperation between the Department of Agriculture and the Patent Office.⁷⁰ Accordingly, the Congress cannot be said to have either solicited Secretary Hyde's opinion as to the scope of

⁶⁸ Senate Report of the Committee on Patent accompanying the Plant Patent Act of 1930, S. Rep. No. 315, 71st Cong., 2d Sess. (1930). See also the discussion of remarks by several Congressmen cited by Petitioner (Pet. Brief at 26) at note 63, *supra* and accompanying text.

⁶⁹ Senate Report, *supra* note 68, at 3.

⁷⁰ Senate Report, *supra* note 68, at 5-6.

the existing patent law or adopted that opinion. The remark of Secretary Hyde in question is, therefore, no more reliable as an indication of Congressional intention than any other comment submitted to Congress before it acts.⁷¹ As noted in *United States v. Fairfield Gloves*, 558 F.2d 1023, 1027 (C.C.P.A. 1977), an opinion authored by Judge Miller, the lone dissenter below and a former U.S. Senator:

Statements made in briefs or in testimony presented at committee hearings cannot be considered as a guide to what Congress intended, since Congress has not delegated to organizations or individuals appearing before its committees the authority to construe a statute.

Accordingly, the quoted remark of Secretary Hyde is without legal effect.

3. There are several plausible explanations for the Plant Patent Act other than that urged by Petitioner

It is argued that there is no possible reason for the addition of language describing various kinds of plants to the categories of statutory subject matter in R.S. 4886 except that such plants were not encompassed within the existing language. However, there are at least two other plausible reasons,⁷² both of which find

⁷¹ Petitioner seeks to buttress the significance of Secretary Hyde's opinion as to the scope of existing patent law, a law which he was not charged with administering, by opining that Secretary Hyde must have had the "advice of expert patent counsel" (Pet. Brief at 26, n.28). Suffice it to say, the existence, content or reliability of any such advice does not appear from the legislative history and must be regarded as pure conjecture.

⁷² See, e.g., Gutttag, *Patentability of Microorganisms: Statutory Subject Matter and Other Living Things*, 13 U. Rich. L. Rev. 247, 263 (1979).

as much support in the legislative history as Petitioner's theory.

The first and most obvious reason for the amendment would be to declare the existence of rights whose existence might otherwise be subject to question. As noted in the CCPA majority opinion, 596 F.2d at 982, plants had been regarded as "products of nature," not resulting from the work of man, and thus not "inventions" within the meaning of the statute.⁷³ In enacting the Plant Patent Act, Congress took great pains to declare that certain works of plant originators were, in fact, "inventions" rather than "products of nature."⁷⁴ Since the pertinent statutory language—"[w]hoever invents or discovers"—was the same both before and after passage of the 1930 Act, extensive consideration by Congress of the "invention" issue is consistent with a desire to declare and clarify existing rights, viz., that certain plants were not products of nature and were thus subsumed within the statutory language relating to inventions even prior to the 1930 Act.⁷⁵

⁷³ See, e.g., *Ex parte Latimer*, 1889 Dec. Comm. Pat. 123 and *Thorne, Relation of Patent Law to Natural Products*, 6 J. Pat. Off. Soc'y. 23 (1923).

⁷⁴ *Senate Report*, *supra* note 68, at 6-9.

⁷⁵ Petitioner seeks to blunt this explanation by urging a lack of legislative awareness of the "product of nature" problem relating to plants. This position cannot be seriously entertained. Fully a third of the Senate Report is devoted to an exhaustive declaration that the work of plant originators constitutes an "invention" rather than a "product of nature." Indeed, the quote from the Senate Report appearing in the text at page 32 of Petitioner's brief, reporting a clear distinction between the discovery of a new variety of plant and discovery of inanimate things such as minerals, was an effort to distinguish new plants from *products of nature*, not from things that were not "alive," as suggested by Petitioner. The quoted passage next notes: "The mineral is cre-

A second rational explanation for enactment of the Plant Patent Act relates to the relaxation of certain formal requirements which had commonly been viewed as imposing substantial impediments to patenting complex organisms such as plants.⁷⁶ This relaxation is evidenced by the amendment to R.S. 4888 by the Plant Patent Act of 1930 to reduce the disclosure requirements for plant inventions.

The question has been raised by Petitioner, however, as to why, if Congress simply sought to relax the disclosure requirements, it was necessary to amend both R.S. 4886 and R.S. 4888. A plausible answer lies in the recognition that amendment of R.S. 4886 to add the

ated wholly by nature unassisted by man." *Senate Report, supra* note 68 at 7. More significantly, even Petitioner concedes that the realization that plants simply found in nature, i.e., products of nature, had to be excluded from any plant patent legislation occurred *during* the legislative process leading to passage of the Plant Patent Act of 1930. Pet. Brief at 34-35.

⁷⁶ See, e.g., the remarks of Commissioner of Patents T. E. Robertson, commenting on S. 3530, the first Senate bill to amend R.S. 4886 to specifically describe plants. Incorporated in a letter of Secretary of Commerce R. P. Lamont read by Chairman A. H. Vestal in hearings before the House Committee on Patents on H.R. 11372, 71st Cong., April 9, 1930, it states that the written description of a plant filed in the Patent Office would be useless and hence could not satisfy the disclosure requirements then embodied in R.S. 4888. See also authorities quoted in note 64, *supra*.

The remarks of Commissioner Robertson are cited as probative of the existing state of the patent law and must be distinguished from the remarks on the same topic by Secretary of Agriculture Hyde quoted above. Commissioner Robertson was the administrative official directly charged with and having experience in administration of the patent laws. As noted by the Ninth Circuit Court of Appeals in a slightly different context, "Courts accord 'great weight' only to the interpretations given a statute by the agency charged with the statute's administration." *Hamilton v. Butz*, 520 F.2d 709, 714 (9th Cir. 1975).

phrase "or who has invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated plant . . ." provided the logical antecedent for the amendment of R.S. 4888 to exempt all "plant patent[s]" from the prevailing disclosure requirements. In order to avoid inclusion of *all* plants, including certain politically controversial sexually reproduced and tuber-propagated plants, within the R.S. 4888 exemption, it would have been necessary to *exclude* certain plants from the existing scope of patentable inventions. Given that the exempted and non-exempted classes of inventions had to be defined somewhere, it was eminently sensible to define those classes in the section of the statute where other groups of inventions were already defined.

It is apparent from the foregoing that the legislative history of the Plant Patent Act is, in all respects, at most neutral on the perceived status of microorganisms under the existing patent law. The legislative history reflects preoccupation with two problems which had to be overcome to allow plants, in the lay sense of the term, to partake of all of the benefits of the patent system—a declaration that they were not products of nature and exemption from disclosure requirements. Petitioner concedes that the Chakrabarty microorganism is not a product of nature, and does not challenge the validity of the practice under *Argoudelis, supra*, whereby the disclosure of the Chakrabarty microorganism was made to conform to existing disclosure requirements. Accordingly, the plethora of material relating to solution of the problems with plants is of no value in determining how microorganisms should be treated under antecedent statutory language.

IV. CONCLUSION

Rcent months have witnessed a multitude of expressions of concern—in the press, in Congress and by the Executive Branch of the government—about the decline of industrial innovation in the United States. Given the vast potential of living organism technology for solving many of the ills besetting the country and for contributing significantly to a turnaround of the innovation crisis, it would be tragic indeed if this Court were to accept the “sky-is-falling” arguments of *Amicus* PBC or the tortured and slavishly technical arguments of Petitioner against its patentability in the abstract. *Amicus* PMA submits that this result need not—and, more importantly, should not—be reached.

Respectfully submitted,

By DONALD R. DUNNER
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER
1775 K Street, N.W.
Washington, D.C. 20006
(202) 293-6850

Counsel for *Amicus* Pharmaceutical
Manufacturers Association

Of Counsel:

CHARLES E. LIPSEY
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER
1775 K Street, N.W.
Washington, D.C. 20006
(202) 293-6850

BRUCE J. BRENNAN
EDWIN C. MULCAHY
Pharmaceutical Manufacturers
Association
1155 15th St., N.W.
Washington, D.C. 20005
(202) 463-2000